UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2272
This Document Relates to All Cases	)	Master Docket Case No. 1:11-cv-05468
	)	Honorable Rebecca Pallmeyer

PLAINTIFFS' STEERING COMMITTEE'S REPLY IN FURTHER SUPPORT OF MOTION FOR AN ORDER RESOLVING DEFENDANT FACT SHEET DISPUTES

Consistent with Defendant's approach since the inception of this multidistrict litigation ("MDL"), the Zimmer Entities seek to use the present motion relating to the scope of Defendant Fact Sheet Discovery as a vehicle to not only limit the scope of this MDL to a greater extent than anticipated by the Judicial Panel for Multidistrict Litigation ("JPML"), but to also limit the obligations imposed by the Federal Rules of Civil Procedure to produce relevant documents and information. As outlined in Plaintiffs' Steering Committee's Brief in Support of Motion for an Order Resolving Defendant Fact Sheet Disputes ("DFS Motion") and reiterated herein, the Court should adopt the form of Defendant Fact Sheet proposed by the Plaintiffs' Steering Committee ("PSC").

I. Plaintiffs' Proposed Definition Of "Plaintiff's Device(s)" Seeks Information Relevant To This Litigation

Plaintiffs' proposed definition of "Plaintiff's Device(s)" seeks information that is relevant to this litigation. As outlined below, Plaintiffs' position regarding the scope of products covered by this MDL has been consistent throughout and the information sought by way of Plaintiffs' version of the Defendant Fact Sheet ("DFS"), and Plaintiffs' definition of "Plaintiff's Device(s)" within the DFS, is relevant to this litigation.

A. The "NexGen High-Flex Knee Implant" Consists Of Multiple Component Parts Relevant To This Litigation

In moving for centralization of these cases Plaintiffs asserted to the JPML that the "NexGen high-flex knee implant is defective."[1] *See* Plaintiffs' Brief in Support of Plaintiff Fred Stone's Motion for Centralization and Transfer of Actions to the Northern District of Illinois or Another More Appropriate Jurisdiction, MDL Case No. 2272, Dkt. 1-1 at 6 (hereinafter "JPML Motion"). As highlighted in the JPML Motion (and elsewhere), the "NexGen high-flex knee implant" consists of multiple component parts:

> ***The NexGen high-flex knee implants*** are made up of three components: 1) a metal femoral component that curves around the bottom of the femur bone; 2) the tibial component which consists of a metal base plate that attaches to the top of the tibia bone and a polyethylene articular surface that rests on the top of the metal tray; and 3) the patella which acts like a knee cap… (emphasis added).

See JPML Motion at 5. Plaintiffs' position that the NexGen high-flex knee implants are a complete knee replacement system has not waivered. *See* JPML Motion at 10 (referring to "Zimmer NexGen high-flex and MIS implants as a ***complete knee replacement system***." (emphasis added)); *see also* Plaintiffs' Technical Memorandum on Knee Anatomy, Total Knee Replacement and the Zimmer NexGen High-Flexion Components and MIS Surgical Technique ("Plaintiffs' Technical Memo.") (Document No. 210) at 6 (noting that "The NexGen TKR was an integrated system combining femoral component, a tibial component, a plastic articulating surface and a plastic replacement for the posterior surface of the patella."); Master Long Form Complaint and Jury Demand ("Master Complaint") (Document No. 211) at ¶ 54 ("NexGen total

[1] Plaintiffs have consistently and continually used the term "NexGen high-flex knee implants" to refer to a collection of component parts as compared to a single component part.

knee replacement is "an integrated system combining a femoral component, a tibial component, a plastic articulating surface and a plastic replacement for the posterior surface of the patella.").[2]

Plaintiffs' position has been, and continues to be, that the various component parts of the NexGen high-flex knee implant work in conjunction with each other and perform as a unified system. None of the component parts work in isolation. Consistent with the aforementioned, at oral argument before the JPML Plaintiffs' counsel reiterated the same: "What is the product? The product is a system. In every document that an investor, a shareholder, the SEC, the public, health care providers, or the FDA receives regarding these products, it is referred to as either a system or a product or a unified system of interchangeable components. It is a knee system…" *See* July 28, 2011, Transcript of JPML Hearing at 5 ("JPML Hearing").

The purported "benefit" of the NexGen high-flex knee implant is that the femoral components (*i.e.*, LPS-Flex, CR-Flex, and the "Gender Solutions" versions thereof) are designed to accommodate higher flexion (up to 155º). *See* JPML Motion at 5 ("The high-flex versions are purported to achieve 155 degrees of flexion, which is 35 degrees more flexion than a standard knee."). *See also* JPML Hearing at 5 ("the flex knee was designed to go to 155 degrees of bending."); Plaintiffs' Technical Memo. at 7 ("The LPS Flex was designed to allow for a maximum flexion of 155 degrees. The NexGen CR Flex followed in 2003, also allowed up to 155 degrees of flexion."). In this regard, the defect that exists in the NexGen high flex knee implant "relates to the flex component." JPML Hearing at 7. "The extra flexion is largely

[2] Zimmer's own documents support Plaintiffs' contention. *See, i.e.*, NexGen LPS-Flex Mobile and LPS-Mobile Bearing Knee Systems Package Insert, attached as Exhibit E to Plaintiffs' Opposition To Defendant's Motion For Protective Order (Document No. 245) (noting that the "NexGen LPS Mobile Bearing Knee systems" consist of a (1) femoral component; (2) tibial component; (3) articular surface component; and (4) patella component).

achieved through a redesign of the femoral component by expanding the size and thickness of the posterior condyle." Plaintiffs' Technical Memo. at 8.

Significantly, Plaintiffs allege that the forces created by the use of the Zimmer high-flex femoral components can not only cause loosening of the femoral component, but can also cause loosening of the tibial tray. Therefore, in any case where a flex femoral component is implanted and the tibial component fails, Plaintiffs allege that the tibial loosening was the result of the defective NexGen high-flex knee implant and, specifically, the flex femoral component. *See* JPML Motion at 1 ("high rate of failure among component**s** making up the Zimmer NexGen knee implant devices." (emphasis added)). *See also* JPML Motion at 2 (referring to high failure rates that have been reported with "NexGen high-flex knee implants," not just flex femoral components); Master Complaint at ¶ 118 ("Loosening can occur with any component of the artificial knee, including the femoral, tibial or patellar component.").

Although Plaintiffs believe that every component part of the Zimmer NexGen high-flex implant is relevant to this litigation, for purposes of the DFS Plaintiffs have requested only that materials and information relating to ***every*** flex femoral component (whether explanted or not) should be produced. In addition, for purposes of the DFS, Plaintiffs have requested only that materials and information relating to Zimmer high-flex knee implant component part that have been explanted should be produced. Such production would not be outside of the scope of products at issue in this MDL as each such component part would either be (1) the flex femoral component part subject of this MDL; or (2) a part of the NexGen high-flex knee implant system that failed due to the flex femoral component part.

B. The NexGen "MIS Tibial Component" Is Not Limited To Only The 5950 Tibial Component

Defendant goes to great lengths to limit the definition of "MIS Tibial Component," in the DFS. However, Defendant's efforts to restrict the DFS definition to only the "5950" are unavailing. At the outset, although Defendant casts Plaintiffs' definition of "Plaintiff's Device(s)" as including "5950 MIS Tibial Component that is implanted…," (*See* Zimmer Entities' Response In Opposition To Plaintiffs' Motion For Order Resolving Defendant Fact Sheet Dispute ("Deft. Opp.") at 3), Defendant's recitation of Plaintiff's requested definition is incorrect. Instead, Plaintiffs define "Plaintiff's Device(s)" as any "MIS tibial component that is the basis of Plaintiff's Complaint." *See* DFS Motion at 1. *See also* DFS Motion, Exhibit A at 1. Along the same lines, Defendant self-servingly injects "5950" language into the JPML Transfer Order by adding "[Total Knee Procedure Stemmed Tibial Component Fixed Bearing Precoat]…" in an effort to limit the JPML interpretation. Such efforts should carry no weight.

Zimmer is responsible for the design, marketing and sale of multiple MIS tibial components. In addition to the 5950 which was the subject of a product recall, there have been other MIS tibial components subject to recall (such as the 5954). Beyond recalled MIS tibial components, there are other MIS tibial components that are marketed by Zimmer, named in cases that are part of this MDL, and that have been used as part of Zimmer's recommended MIS procedures. As noted in Plaintiffs' JPML Motion, "where the use of a drop down stem was not used, the [MIS tibial component] becomes loose." JPML Motion at 7.[3] In short, there is nothing within the JPML order that specifically limits this litigation to the MIS 5950.

[3] In their technical presentation Plaintiffs also referred to multiple MIS tibial components subject to this litigation. *See* Technical Memo. at 9 (referring to costs of tibial components and referencing multiple MIS options).

Defendant's position regarding the definition of "Plaintiffs' Device(s)" as it relates to the DFS represents nothing more than another step in an ongoing attempt to limit the number of cases in this MDL, and is a continuation of its ongoing objection to and refusal to accept the JPML Order for centralization of these cases. In initially opposing centralization Defendant recognized what Plaintiffs have continually argued, that "[e]very total knee prosthesis includes a tibial plate (or 'tray'), a femoral component, and a weight-bearing plastic insert between the two ('tibial insert' or 'articulating surface')." *See* Brief Of Zimmer Entities In Opposition To Plaintiff Fred Stone's Motion For Consolidation And Transfer Of Actions To The Northern District Of Illinois Or Another More Appropriate Jurisdiction ("JPML Opp.") at 3. However, Defendant now looks to "blow up" the manner in which its NexGen high flex knee prosthesis and MIS tibial components were approved, designed and marketed in order to create a false perception that discovery relating to multiple component parts is unwarranted.

Contrary to the overwhelming picture painted by Defendant, for purposes of the DFS Plaintiffs only seek documents and information related to the flex femoral component and/or MIS Tibial Component at the core of and individual's complaint, as well as any related component parts that were explanted at the time of revision. Each of the aforementioned component parts, in addition to all other component parts implanted as part of the Zimmer knee prosthesis is relevant to this litigation. However, Plaintiffs have limited their DFS requests as a means of compromise.[4]

[4] Defendant's reference to products that "did not fail but have been explanted" creates a circular argument. In essence, Defendant demands that Plaintiffs provide evidence that a component part "failed" before it will produce documents and information needed to support an argument that a component part failed. In contrast to Defendant's position, Plaintiffs' proposal provides deference to healthcare providers by limiting the DFS requests to the flex femoral component and/or MIS Tibial Component and any other component part that was explanted, assuming that an explanting surgeon removed only those component parts that caused concern.

The case law cited by Defendant in support of its position is easily distinguishable. In *Piancenti v. General Motors, Corp.*, 173 F.R.D. 221 (N.D. Ill. 1997) and *Gibson v. Ford Motor Co.*, 510 F.Supp. 2d 1116 (N.D. Ga. 2007), both cases cited by Defendant for the proposition that discovery into unrelated products should not be permitted, the courts were asked to determine whether discovery related to different vehicle models manufactured by the same defendant was permissible. *See Piancenti*, 173 F.R.D. at 225; *Gibson*, 510 F.Supp. 2d at 1118. In contrast to the cases cited by Defendant, the DFS does not seek information relating to different products or different models. Instead, it seeks information relating to the various component parts that make up the Zimmer high-flex knee implant at issue. By analogy, Defendant's request to limit the definition of "Plaintiff's Device(s)" in the present matter would be akin to prohibiting discovery on a vehicle's handling and stability because it was the roof that was crushed in an accident, not the suspension or braking.

As outlined above, from the time centralization was sought via the JPML, during their technical presentation to the Court and through the filing of a Master Complaint, Plaintiffs have presented a consistent case theory as it relates to the NexGen high-flex knee implants – that the design of the flex femoral component, which is part of an integrated, uniform system, can cause loosening to occur with any component of the artificial knee, including the femoral, tibial or patellar component. Likewise, as it relates to MIS Tibial Components, Plaintiffs have consistently presented arguments that were not limited to only the 5950. Based upon such allegations, discovery related to all component parts is relevant and warranted. *See Schaap v. Executive Indus., Inc.*, 130 F.R.D. 384, 386, 387 (N.D. Ill. 1990) (holding that discovery of information concerning component parts was permissible). For purposes of discovery and the DFS, Defendant does not get to mold and shape Plaintiffs' theory to its liking. *See Amcast*

Industrial Corp., v. Detrex Corp., 138 F.R.D. 115, 118 (N.D. In. 1991) ("Consistently with the notice-pleading system established by the [federal rules], discovery is not limited to issues raised by the pleadings, for discovery itself is designed to help define and clarify the issues.").

II. Plaintiffs Have A Right To Information Relating To Communications Between Defendant's Employees And Plaintiffs' Implanting Surgeons Or Their Groups Or Practices

As noted in the DFS Motion, information relating to relationships, ***communications*** and compensation by and between Defendant and Plaintiffs' healthcare providers is significantly relevant to the decision-making process employed in recommending and using the devices implanted in Plaintiffs. *See* DFS Motion at 6 (emphasis added). Although Defendant acknowledges the same (*see* Deft. Opp. at 10), it argues that the provision of standardized materials such as Package Inserts, Surgical Techniques, and marketing materials supplied to physicians satisfies it obligations relating to communications with healthcare providers. Defendant's offer falls woefully short, depriving Plaintiffs of information relating to specific instances where Defendant engaged specific physicians but did not leave behind standardized propaganda. Likewise, that Defendant is producing custodial files on a rolling basis inclusive of employees who have communicated with surgeons during the development of a new product does not serve individual Plaintiff's discovery needs.

To the contrary, during the pendency of such "rolling" productions Defendant will be noticing and taking the depositions of treating physicians. During said depositions Plaintiffs will be at a significant disadvantage, unaware of whether and to what extent Zimmer employees may have interacted with the physicians. Because information relating to healthcare provider contact is relevant and necessary for Plaintiffs to participate in treating physician depositions, and because the DFS is the only way for individual Plaintiffs to get such information before

depositions are scheduled, the prejudice that befalls Plaintiffs by relieving Defendant of its discovery obligation far outweighs any burden that may be shouldered by Defendant.

III. Conclusion

For the foregoing reasons Plaintiffs respectfully request that this Court adopt Plaintiffs' recommendations regarding the DFS and (1) broadly define "Plaintiff's Device(s)" to include the Zimmer NexGen high-flex femoral component and/or MIS tibial component that is the basis of Plaintiff's Complaint and any other Zimmer component part that was revised (or that a physician has suggested will need to be revised); and (2) require Defendant to provide documents and information relating to instances where Defendant's employees communicated, detailed, marketed or sold to Plaintiff's implanting surgeon.

Dated: February 22, 2012

Respectfully submitted,

PLAINTIFFS' STEERING COMMITTEE

/s/ *Peter J. Flowers*

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CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2012, I electronically filed the foregoing document with the clerk of the court for the U.S. District Court, Northern District of Illinois, using the electronic case filing system of the Court.

/s/ Peter J. Flowers